

| <b>Notice of Allowability</b> | Application No. | Applicant(s)   |  |
|-------------------------------|-----------------|----------------|--|
|                               | 09/120,044      | MINETTI ET AL. |  |
|                               | Examiner        | Art Unit       |  |
|                               | S. Devi, Ph.D.  | 1645           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to Applicants' amendment filed 10/06/03.
- The allowed claim(s) is/are 35-37, 42-51, 53, 61-76, 78, 79, 81 and 82.
- The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - All
  - Some\*
  - None
 of the:
  - Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - The translation of the foreign language provisional application has been received.
- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - hereto or 2)  to Paper No. 37.
  - including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

- DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

|   |  |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.   |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment         |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9 <input checked="" type="checkbox"/> Other Attachment.                    |

## **ATTACHMENT TO NOTICE OF ALLOWABILITY**

### **After-Final Amendment**

**1)** Acknowledgment is made of Applicants' after-final amendment filed 10/06/03 in response to the final Office Action mailed 05/06/03.

### **Examiner's Amendment**

**2)** An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization for this Examiner's amendment was provided by Ms. Evelyn Kwon in a telephone interview on 07 November 2003:

This application has been amended as indicated below:

- (a) In line 2 of claim 35, the limitation --wild-type-- is inserted before the recitation 'pneumolysin'.
- (b) In line 3 of claim 35, the limitation 'a sequence' is replaced with --the amino acid sequence--.
- (c) In line 4 of claim 35, the limitation 'single amino sequence substitutions occur' is replaced with --said one amino acid substitution occurs--.
- (d) In line 5 of claim 35, the limitation 'positions' is replaced with --position--.
- (e) In line 6 of claim 35, the limitation 'substitutions of more than one amino acids' is replaced with --said more than one amino acid substitutions--.
- (f) In lines 10 and 11 of claim 35, the limitation 'having at least one amino acid substitution' has been deleted.
- (g) In line 1 of claims 36, 37 and 42, the limitation 'polypeptide' is replaced with --modified pneumolysin polypeptide--.
- (h) In line 2 of claims 36 and 37, the limitation --the hemolytic activity of the-- is inserted before the limitation 'wild-type'.
- (i) In line 2 of claim 42, the limitations 'pNVJ20' and 'pNVJ45' have been deleted.
- (j) From lines 2-5 of claim 53, the limitations: 'wherein the polypeptide is soluble .....encoding a pneumolysin polypeptide, and' have been deleted.

Serial No: 09/120,044

Art Unit: 1645

- (k) In line 3 of claim 61, the limitation 'derived' has been deleted.
- (l) In line 3 of claim 65, the limitation 'or hydroxyproline' has been deleted.
- (m) In line 3 of claim 66, the limitations ', arginine or histidine' have been deleted.
- (n) In line 3 of claim 67, the limitations 'leucine, glycine, alanine,' have been deleted.
- (o) In line 3 of claim 71, the limitation '255.' has been replaced with the limitations --, and an additional substitution at position 172.--
- (p) Claims 77 and 80 have been canceled.
- (q) The recitation: 'alanine at position 172,' in line 2 of claim 72 as well as the term 'and' in line 3 of claim 72 have been deleted; and the limitation '255.' in line 3 of the claim is replaced with --255, and alanine at position 172.--
- (r) In line 3 of claim 74, the recitations 'and lysine at position 148.' is replaced with --148, and glutamic acid at position 127.--
- (s) New claims 81 and 82 have been added as shown below:
  - Claim 81. (New) The modified pneumolysin polypeptide according to claim 72, wherein the modified pneumolysin polypeptide is pNVJ45.--
  - Claim 82. (New) The modified pneumolysin polypeptide according to claim 74, wherein the modified pneumolysin polypeptide is pNVJ20.--
- (t) The following paragraph is inserted on page 1 of the specification above the section 'FIELD OF THE INVENTION'.
  - The instant application claims domestic priority to the provisional applications, 60/073,456 filed 02/02/1998 and 60/053,306 filed 07/21/1997.--

#### **Status of Claims**

3) Claims 35, 53, 61, 62 and 65-80 have been amended via the amendment filed 10/06/03.

Claim 60 has been canceled via the amendment filed 10/06/03.

Claims 35-37, 42, 53, 61, 65-67 and 71-74 have been amended via this Examiner's amendment.

Claims 77 and 80 have been canceled via this Examiner's amendment.

New claims 81 and 82 have been added via this Examiner's amendment.

Claims 35-37, 42-51, 53, 61-76, 78, 79, 81 and 82 are under examination.

Serial No: 09/120,044  
Art Unit: 1645

#### **Rejection(s) Moot**

- 4) The rejection of claim 80 made in paragraphs 25(b), 25(f), 25(g) and 25(h) of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 5) The rejection of claims 60 and 77 made in paragraph 25(i) of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

#### **Rejection(s) Withdrawn**

- 6) The rejection of claims 35-37, 42 and 60-80 made in paragraph 24 of the Office Action mailed 08/14/02 (paper no. 37) and made/maintained in paragraph 25 of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, first paragraph, as being non-enabled, with regard to the scope, is withdrawn in light of Applicants' amendments and/or amendments made via this Examiner's amendment.
- 7) The rejection of claim 35 made in paragraphs 25(a) and 25(c) of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments and/or amendments made via this Examiner's amendment.
- 8) The rejection of claims 65-68 made in paragraphs 25(d) and 25(e) of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments and/or amendments made via this Examiner's amendment.
- 9) The rejection of claims 36-37, 42, 61-76, 78 and 79 made in paragraph 25(i) of the Office Action mailed 05/06/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments and/or amendments made via this Examiner's amendment.
- 10) The rejection of claim 53 made in paragraph 26 of the Office Action mailed 05/06/03 under 35 U.S.C. § 102(b) as being anticipated by Lock *et al.* (*Microb. Pathogen.* 21: 71-83, 1996 - Applicants' IDS), or Lee *et al.* (*Vaccine* 12: 875-878, 1994, already of record), or Paton *et al.* (*Infect. Immun.* 59: 2297-2304, 1991 - Applicants' IDS), or Alexander *et al.* (*Infect. Immun.* 62: 5683-5688, 1994, already of record), is withdrawn in light of Applicants' amendments to the claim.

#### **Remarks**

- 11) Claims 35-37, 42, 53, 61-72, 81, 73, 74, 82, 75, 76, 78, 79 and 43-51, now renumbered as

Serial No: 09/120,044

Art Unit: 1645

claims 1-3, 4, 5, 6-17, 18, 19, 20, 21, 22, 23, 24, 25 and 26-34 respectively, are allowed.

**12)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

**13)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER